DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
DRC-NEI-35 m2/15?

60 8th Street, N.E.
Atlanta, Georgia 30309

August 3, 1999

FEDERAL EXPRESS

Katsushi Sugano
Vice President
SAS Foods, Inc.
2395 Pleasantdale Rd.
Doraville, GA 30340

Warning Letter
(99-ATL-26)

Dear Mr. Sugano:

On April 28 & 30, 1999, the Food and Drug Administration (FDA) conducted an inspection of your importer business located in Doraville, GA. Our investigator documented deviations from FDA's seafood importing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123.12). These deviations cause the seafood products imported and stored by our firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations found are as follows:

1. The written product specifications for frozen baked bonito are inadequate in that they lack safety specifications, such as histamine content and/or pathogen limits. [21 CFR 123.12(a)(2)(I)]

2. The written product specifications for frozen yellowtail fillets are inadequate in that they lack safety specifications such as histamine content and/or pathogen limits, and certification that the fish was not harvested from waters containing ciguatoxin. [21 CFR 123.12(a)(2)(I)]

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products imported, processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulations.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Sheryl R. Cruse, Compliance Officer, U. S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, GA 30309.

Sincerely,

Roger E. Kline

Roger E. Kline, Acting Director
Atlanta District